Development and Preliminary Validation of Rapid Progestin-Based Endocrine Disruption Screening Assay

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Concerns regarding both the presence of endocrine disruptors in food, water, or other environmental media as well as the potential risk they pose to humans and wildlife have been growing in recent years. Passage of the Food Quality Protection Act and Amendments to the Safe Drinking Water Act reflect these concerns and required the U.S. Environmental Protection Agency (EPA) to develop a screening program to determine whether certain substances may have an endocrine effect in wildlife and humans. This project will result in validation of an assay that tests substances that might disturb reproductive and developmental processes during the life cycle of animals by interfering with the endocrine system. The primary goal is to standardize, validate, and commercialize an amphibian life cycle model using Xenopus as a system for evaluation of endocrine-disrupting chemicals (EDCs) found in the workplace or the environment. Specifically, we will standardize and validate an *X. tropicalis* assay designed to evaluate the effect of EDCs on various aspects of the amphibian life cycle. Because none of the currently developed EDC test systems are capable of specifically addressing life cycle effects in amphibians, and the Endocrine Disruptor Screening Program developed for EPA by the Endocrine Screening and Testing Committee is labor intensive, the successful completion of this amphibian life cycle model will provide the scientific community with a non-mammalian, cost-effective, rapid, reliable method of prescreening EDCs. The ability to rapidly and cost-effectively screen for and evaluate the mechanisms of EDCs is an attractive alternative to the current laborious and expensive testing systems used today. Increasing concerns over the widespread finding of EDCs in the environment have dramatically increased the need for standardized assays, such as the Xenopus life cycle model, because no other assay of this type is available today. Current estimates indicate that nearly 50,000 chemicals in the United States may require EDC testing with models like the amphibian life cycle assay. Overall, this volume of work has the potential of generating approximately $125 billion over the next 10-15 years. Realistically, we anticipate that, based on the high volume of work generated by this need for cost-effective testing of chemicals, revenues of over $5 million could be generated over the next 2 years, and more than $25 billion over the next 10 years.

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